

REMARKS

Claims 1-16 have been amended to reflect the nature of former claim 18 as a method of use claim. Support for claim 1 as amended is found in paragraph 23. Support for inclusion of pharmaceutically acceptable salts is found in paragraph 43. The list of conditions included in claim 1 is also found in paragraph 23 as well as on pages 8-10 of the specification. Claim 16 has been amended to correspond to the altered format of claim 1. Claims 6 and 8 have been canceled as inconsistent or redundant. Claims 17 and 18 have been canceled as clearly irrelevant in view of the amendment to claim 1.

However, compounds are claimed in new claim 19 which is limited to the structure set forth in claim 3. Dependent claims 20-31 correspond to former claims 5, 7, and 9-17. Accordingly, no new matter is added and entry of the amendment is respectfully requested.

The Restriction Requirement

As noted above, as applicants believe that generic claims are now allowable, and the restriction requirement was directed only to an election of species, the withdrawn claims have not been canceled.

The Information Disclosure Statement

Applicants note the advice that the previously filed Information Disclosure Statements have not completely been considered. Supplementary Information Disclosure Statements are being submitted under separate cover.

Specification

The suggested correction has been made.

The Rejection Under 35 USC § 112

This rejection was applied only to claims 17 and 18 which have been canceled, but in view of the amendment to claim 1, applicants will respond. The Office cites four of the Wands factors as assertedly undermining the patentability of former claim 18. Many of the issues raised have been addressed by amendment.

First, as to the first factor discussed by the Office: the nature of the invention, state and predictability of the art and relative skill level, the Office acknowledges that the skill in the art is high. In addition, the asserted unpredictability with respect to cancer appears irrelevant in view of the amendment to the claims which specifies a number of conditions, none of which is cancer. It is well established in the art as noted in the specification in paragraphs 23-26 that the specified conditions in claim 1 are all known to be associated with inappropriate N-type or T-type calcium ion channel activity. Accordingly, as to the first Wands factor pointed out by the Office, patentability appears justified.

As to the second Wands factor, the breadth of the claims, again, the conditions specifically listed in claim 1 limit its scope and the compounds are all related structurally. Accordingly, the breadth of the claims is appropriate.

As to the third factor, applicants have demonstrated activity with regard to N-type and T-type channels in representative members of the claimed genus; thus, there is working example support for the claim scope.

As to the fourth factor, the quantity of experimentation necessary, it is believed that the foregoing discussion makes clear that undue experimentation would not be necessary. The Office has marshaled no evidence other than that in factors 1-3, to which applicants have responded, in support of its conclusion that undue experimentation would be necessary.

Accordingly, applicants believe that claim 1, has more particularity than rejected claim 18, is fully supported by the specification and meets the requirements of 25 USC § 112, paragraph 1.

The Rejection Under 35 USC § 112 Indefiniteness

Claim 1, which replaces claim 18 has been clarified by specifying particular diseases. Accordingly, this basis for rejection may be withdrawn.

The Rejection Under 35 USC § 102

Claims 1, 3, 5, 7-10, 12, 13 and 17-18 were rejected under this section over Connor (US 6,458,781). Claim 1 as amended and the newly proposed claims to compounds are not anticipated by Connor because the presence of X¹ is required. The compound noted by the Office in example 17 of Connor is the only relevant compound in that disclosure and in that case, there is no linker between Ar and the piperazine ring. Accordingly, the claims as now proposed are free of this rejection.

The Rejection Under 35 USC § 103

Claims 1, 7, 10-12 and 17 were rejected as assertedly obvious over Okamura, et al. (US 5,866,574). The Office asserts that although the compounds of Okamura do not anticipate the generic structure of claim 1, the only difference is in the requirement that X² contain at least five members whereas what would correspond to X² in Okamura's cited compound contains only four. While applicants do not subscribe to this argument (because taken as a whole, the structures described by Okamura do not closely resemble those of the present invention) the claims as amended clearly are not suggested by Okamura. Okamura describes only compounds that are therapeutic agents for pancreatitis because of their properties of inhibiting adenosine uptake.

The present claims 1-5, 7 and 9-16 are directed to methods to treat conditions benefited by modulation of N-type and/or T-type calcium channel activity which conditions are articulated in

claim 1 and have no relation to pancreatitis. It is also noted that claim 18, a broader form of current claim 1 was not included in this rejection. Thus, as to these claims, Okamura clearly does not suggest the subject matter set forth therein.

As to new claims 19-31, directed to compounds, applicants note that claim 3 was not included in the rejection over Okamura and the scope of new claim 19 is that of claim 3. Claims 20-28 and 30 depend from claim 19 and are thus free of this rejection as well. Claim 29 corresponds to former claim 16 which also was not included in this rejection and thus claim 29 and its dependent claim 31 are free of this rejection.

In view of the amendment to the claims and the foregoing discussion, the rejection over Okamura, et al. may properly be withdrawn.

Double-Patenting

Claim 1 was rejected as assertedly double-patenting over certain claims in US Patent 6,943,168. A terminal disclaimer with regard to this patent is enclosed.

Conclusion

Claims 1-5, 6 and 9-16 have been amended to read on the subject matter embraced by former claim 18 which has been canceled. The claim wording has been altered, however, to make specific the nature of the conditions that are to be treated. The assertedly unpredictably treatable condition of cancer is not included among these. As presently drawn, these claims are in compliance, then, with 35 USC § 112, paragraphs 1 and 2. Claims to the compounds, now claims 19-31, were not subject to this rejection.

Claim 1 has also been amended to avoid accidental anticipation by Connor and to distinguish clearly Okamura. New claims 19-28 and 30 correspond to the scope of former claim 3 (as adjusted by the amendment to claim 1 and thus also containing the amendment to avoid Connor). Claim 3 was not included in the rejection over Okamura. Thus, claims 19-28 are also free

of the art. Similarly, claims 29 and 31 are of the scope of claim 16 which was not rejected over any art. In view of the foregoing, applicants believe that claims 1-5, 7, 9-16 and 19-31 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 381092000624. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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